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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,442	06/11/2001	Vincent Dubois	COUL-015/02US	3549

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,442	DUBOIS ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-117* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group A (Inventions I to VII), drawn to compounds and conjugates:

I. Claims 1-3, 5-32, and 37-38, drawn to a compound comprising a therapeutic agent, an oligopeptide, a stabilizing group and optionally, a linker group not cleavable by TOP, classified in class 530, subclass 329, for example.

II. Claim 4, drawn to a compound comprising a therapeutic agent, an oligopeptide, a stabilizing group and optionally, a linker group cleavable by a trouase, classified in class 530, subclass 326, for example.

III. Claim 33, drawn to an oligopeptide selected from the group consisting of D-AlaThiβAlaβAlaLeuAlaLeu (SEQ. ID. NO.:1), for example, classified in class 530, subclass 332, for example.

IV. Claims 34-36, drawn to a conjugate comprising an oligopeptide from the group consisting of D-AlaThiβAlaβAlaLeuAlaLeu (SEQ. ID. NO.:1), for example, classified in class 530, subclass 300, for example.

V. Claim 55, drawn to an article of manufacture for diagnosis or assay, classified in class 530, subclass 329, for example.

VI. Claim 116, drawn to a compound selected from the group consisting of Suc-βAla-Leu-Ala-Leu-Dox, for example, classified in class 530, subclass 330.

VII. Claim 117, drawn to a compound selected from the group βAla-Leu-Ala-Dox, for example, classified in class 530, subclass 331, for example.

Group B (Inventions VIII and IX), drawn to methods of treating a patient:

VIII. Claims 39-44, drawn to a method for treating a patient by administering a compound comprising a therapeutic agent, an oligopeptide, a stabilizing group and optionally, a linker group not cleavable by TOP, classified in class 530, subclass 329, for example.

IX. Claim 51, drawn to a method of treating resistance to a therapeutic agent, classified in class 530, subclass 326, for example.

Group C (Inventions X to XVI), drawn to methods of drug design and synthesis:

X. Claims 45-50, drawn to a method of designing a prodrug for administration, classified in class 530, subclass 330, for example.

XI. Claim 52-54, drawn to a method for decreasing toxicity of a therapeutic agent, classified in class 530, subclass 335, for example.

XII. Claims 56-58, drawn to a method of removing free therapeutic agent, classified in class 530, subclass 344, for example.

XIII. Claims 59-66, drawn to a method of making a prodrug, classified in class 530, subclass 338, for example.

XIV. Claims 67-76, drawn to a method of making a prodrug compound, classified in class 530, subclass 335, for example.

XV. Claims 77-106, drawn to a method for making a prodrug compound, classified in class 530, subclass 334, for example.

XVI. Claims 107-115, drawn to a method for making a prodrug compound, classified in class 530, subclass 333, for example.

The inventions are distinct, each from the other because of the following reasons:

Group A Inventions:

Inventions I to VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ with respect to structure and function. For example, Inventions I and II contain oligopeptides that possess different cleavable groups (i.e.- TOP cleavable vs. trouase cleavable) within the polypeptide, as well as different amino acid sequences, thereby rendering each product patentably distinct. With regard to Inventions III to VII, each individual Invention recites different oligopeptides, oligopeptide conjugates and peptide compounds. These Inventions are patentably distinct inventions because they do not share the same oligopeptides and amino acid sequences and because each product would have different functions,

thereby leading to different effects. It is further noted that a search conducted for one Invention would not necessarily lead to the discovery of any other Invention, thereby leading to a burden of search on the Examiner.

Group B Inventions:

Inventions VIII to IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ with respect to structure and function. For example, Inventions VIII and IX contain distinctly different method steps, whereby the method of Invention VIII is directed towards treating a patient and Inventions IX is directed towards treating resistance to a therapeutic agent. Therefore, the methods of Inventions VIII and IX are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. It is further noted that a search conducted for one Invention would not necessarily lead to the discovery of any other Invention, thereby leading to a burden of search on the Examiner.

Group C Inventions:

Inventions X to XVI, directed towards methods for making prodrug compounds, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ with respect to structure and function. For example, Inventions X to XVI contain distinctly different synthetic method steps. Therefore, the methods of Inventions X to XVI are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. It is further noted that a search conducted for one Invention would not necessarily lead to the discovery of any other Invention, thereby leading to a burden of search on the Examiner.

Groups A and B are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case as evidenced by the claims, themselves, the methods may be carried out with numerous oligopeptides, where the oligopeptide may contain any, or none, of the following moieties: a linker group, a therapeutic agent, a TOP cleavable sequence, a trouase cleavable sequence and non-genetically encoded amino acids.

Groups A and C are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as evidenced by the claims, themselves, the methods recited in Groups C may be carried out to create oligopeptides containing a variety of amino acid combinations in a variety of polypeptide chain lengths.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: oligopeptide sequence (i.e.- SEQ. ID. NO. 4). Currently, claims 1-35 and 37-117 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: stabilizing group. Currently, claims 1-29 and 35-115 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: therapeutic agent. Currently, claims 1-29, 32, 35-54, 56-71,76-82, and 84-115 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: linker group. Currently, claims 1-29, 37-44, 51, and 55 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: medical condition. Currently, claims 43 and 44 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: polymeric resin/ scavenger resin. Currently, claims 56-58 and 97-99 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: activating agent. Currently, claims 59-83, 85-89, and 92-115 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: deprotecting agent. Currently, claims 59-66 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: deprotecting enzyme. Currently, claims 72, 100, 101, and 103-106 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: enzyme associated with the target cell. Currently, claims 1-3, 37, 39, and 42-44 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: trouase. Currently, claim 4 and 40 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: a pharmaceutically acceptable carrier. Currently, claims 37 and 38 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: target cell. Currently, claims 1-29, 37-44, and 51 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: marker. Currently, claim 55 is generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: reagent for identifying marker. Currently, claim 55 is generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-1600. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

Andrew D. Kosar
20 May 2004

PATRICIA LEITH
PRIMARY EXAMINER